

REMARKS/ARGUMENTS

Claims 1-4 and 17-20 are currently pending. In response to the Office Action, Applicant has amended Claims 1-4 and 17-18, which when considered with the following remarks, is deemed to place the present application in condition for allowance. In particular, Claims 1-4 and 17-18 have been amended to remove the “pharmaceutical” and “administration to an animal” language from the claims. Support for these amendments can be found throughout the specification and claims, as originally filed, and in particular in Claims 1-4, and 17-19. No new matter has been added. Claims 19 and 20 have been cancelled.

In the Office Action, Claims 1-4 and 17-20 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner found “1) no evidence of a nexus between the reduction of BC200 levels, as by antisense-mediated degradation of BC200 RNA, and the remediation of any neurological condition or cancer; 2) that residues 1-122 of BC200 RNA are highly homologous to Alu repetitive elements which are found in high copy numbers in primate genomes (page 5 of 60/425475), and that therefore antisense oligonucleotides against residues 1-122 of BC200 RNA, as embraced by instant claim 1, would likely hybridize to a number of off-target elements as well as BC200 RNA; and 3) that at the time of filing the delivery of therapeutically effective amounts of antisense oligonucleotides to cells in vivo in a living animal, especially cells in the central nervous system, was highly unpredictable.” (Office Action, pages 4-5).

However, the Examiner has contended that the rejection of Claims 1-4 and 17-20 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement would be overcome if the “pharmaceutical” and “administration to an animal” language were removed from the instant claims. (Office Action, page 9). While Applicant respectfully disagrees that the instant application is not enabled for all claims set forth therein, in order to advance the prosecution of the application, Applicant has amended Claims 1-4 and 17-18 to remove the “pharmaceutical” and “administration to an animal” language from the claims. Accordingly, the rejection of Claims 1-4 and 17-20 under 35 U.S.C. § 112, first paragraph for

allegedly failing to comply with the enablement requirement, should be reconsidered and withdrawn.

In the Office Action, Claims 1-4 and 17-20 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 1-7 of U.S. Patent No. 5,670,318 (“the ‘318 patent”) in view of Ellington et al. (1998) “Synthesis and Purification of Oligonucleotides” in *Current Protocols in Molecular Biology* 2.11.1-2.11.25 (John Wiley & Sons, Inc.) (“Ellington et al.”), Beaucage (1993) “Oligodeoxyribonucleotides synthesis. Phosphoramidite approach” *Methods in Mol. Biology* 20:33-61 (“Beaucage et al.”), and Caruthers et al. (1987) “Chemical synthesis of deoxyoligonucleotides” *Methods in Enzymology* 154:287-313 (“Caruthers et al.”). Applicant respectfully requests that the Examiner hold in abeyance the rejection of Claims 1-4 and 17-20 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-7 of the ‘318 patent in view of Ellington et al., Beaucage, and Caruthers et al., until the presently claimed subject matter is deemed allowable. At that time, Applicant agrees to revisit this rejection and the necessity for filing a terminal disclaimer.

In the Office Action, Claims 1-4 and 17-20 have been rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 1-7 of U.S. Patent No. 5,736,329 (“the ‘329 patent”) in view of Ellington et al., Beaucage, and Caruthers et al. Applicant respectfully requests that the Examiner hold in abeyance the rejection of Claims 1-4 and 17-20 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-7 of the ‘329 patent in view of Ellington et al., Beaucage, and Caruthers et al., until the presently claimed subject matter is deemed allowable. At that time, Applicant agrees to revisit this rejection and the necessity for filing a terminal disclaimer.

In the Office Action, Claims 1-4 and 17-20 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting as allegedly unpatentable over claims 17-19 of copending U.S. Patent Application No. 10/503,782 in view of the ‘318 patent, Ellington et al., Beaucage, and Caruthers et al. Applicant respectfully requests that the Examiner hold in abeyance the rejection of Claims 1-4 and 17-20 on the grounds of nonstatutory obviousness-type

double patenting as being unpatentable over Claims 17-19 of U.S. Patent Application No. 10/503,782 in view of the '318 patent, Ellington et al., Beaucage, and Caruthers et al., until the presently claimed subject matter is deemed allowable. At that time, Applicant agrees to revisit this rejection and the necessity for filing a terminal disclaimer.

In the Office Action, Claims 1-4 and 17-20 have been rejected under 35 U.S.C. 103(a) as allegedly obvious over the '318 patent in view of Ellington et al., Beaucage, and Caruthers et al. In particular, the Examiner concluded that "the instantly claimed pharmaceutical compositions are prima facie obvious as the preparation of the BC200 oligonucleotide probes disclosed by Tiedge et al. would necessarily involve washing, eluting, and/or resuspending said probes in an aqueous solvent, water or buffer of physiological pH for subsequent analysis and use as a biochemical reagent." (Office Action, page 19). However, it is respectfully submitted that even if one of ordinary skill in the art were to combine the cited references in the manner suggested by the Examiner, one of ordinary skill in the art would not arrive at the present invention, as currently amended.

"Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so." MPEP, Section 2143.01, citing *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006).

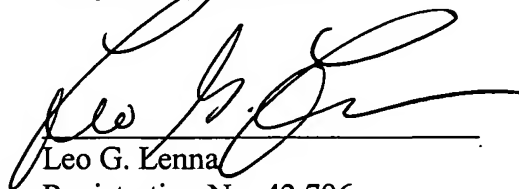
The '318 patent, Ellington et al., Beaucage, or Caruthers et al., taken alone or in combination, do not teach or suggest a composition comprising a therapeutically effective amount of the antisense molecules of Claims 1-4, 17-18, and 20 *admixed* with an acceptable carrier. Indeed, the '318 patent is concerned with the preparation of sequences for use as probes in detecting complementary sequences for diagnostic purposes. Ellington et al., Beaucage, and Caruthers et al. are each concerned with methods for making and purifying oligonucleotides and oligodeoxynucleotides. Specifically, Ellington et al., Beaucage et al., and Caruthers et al. are concerned with methods for making and purifying oligonucleotides and oligodeoxynucleotides in which the final oligonucleotide product is either eluted and pooled in doubly distilled water or resuspended in water or a Tris-EDTA buffer.

Notably, none of the references cited by the Examiner involve oligonucleotides which are admixed with an acceptable carrier. In stark contrast, the present invention requires that the antisense molecules used therein are *admixed* with an acceptable carrier. While admixing components inherently involves obtaining a homogenous mixture thereof, eluting and pooling components in doubly distilled water or resuspended in water or a Tris-EDTA buffer, as taught by Ellington et al., Beaucage, and Caruthers et al., do not. Accordingly, even if one of ordinary skill in the art were to combine the cited references in the manner suggested by the Examiner, one of ordinary skill in the art would not arrive at the present invention, as currently amended. Hence, for the reasons stated above, withdrawal of the rejection of claims 1-4 and 17-20 under 35 U.S.C. §103(a) over the '318 patent in view of Ellington et al., Beaucage, and Caruthers et al. is respectfully requested.

In view of the foregoing remarks and amendment, it is respectfully submitted that all claims pending herein are in condition for allowance. Please contact the undersigned should there be any questions or concerns.

Early and favorable consideration of the case is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leo G. Kenna', written over a horizontal line.

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